

**REMARKS/ARGUMENTS**

Claims 1-10 and 12-21 are pending in the subject application. Claims 1-10 and 12-21 are rejected. Applicants have hereinabove amended 18, and added new claims 28 and 29. Accordingly, upon entry of this Amendment, claims 1-10 and 12-21, as amended, and new claims 28 and 29 will be pending and under examination.

Applicants respectfully request the Examiner to enter this Amendment into the record since the amendments to the claims hereinabove and the remarks/arguments set forth below place the subject application in condition for allowance, or at the very least reduces the number of issues on appeal.

Applicants maintain that the amendments to claim 18 do not raise any new matter, and that the claims, as amended, are fully supported by the specification as originally filed.

Applicants also maintain that new claims 28 and 29 do not raise any new matter, and that the new claims are fully supported by the specification as originally filed. Support for the amendments to new claims 28 and 29 is found, *inter alia*, in the specification as follows: page 9, lines 7-13, page 10, lines 6-7, and page 10, line 16 to page 12, line 15; page 27, line 21 to page 28, line 4.

In making these amendments, applicants neither concede the correctness of the Examiner's rejections in the February 19, 2010 Final Office Action, nor abandon the right to pursue in a continuing application embodiments of the invention no longer claimed in the subject application.

In view of the arguments set forth below in this Amendment, and claim amendments hereinabove, applicants maintain that the Examiner's rejections made in the

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February 19, 2010 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

**Claim Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)**

The Examiner states that claims 18-21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner alleges the specification does not provide enablement for a method that does not administer the carrier specifically to a site of endothelial cell tissue damage.

In response to the Examiner's rejection to claims 18-21, but without conceding the correctness thereof, applicants note that claim 18 has been amended. Amended claim 18 now recites "[a] drug control method comprising *in vivo* administering the pharmaceutical composition of claim 12; allowing said composition to accumulate on a damaged endothelial cell site of a tissue; and allowing the drug to act on the damaged endothelial cell site." Hence, the Examiner's rejection to claims 18-21, as amended, is obviated.

In view of the above remarks, applicants maintain that claims 18-21, as amended, satisfy the requirements of 35 U.S.C. § 112, first paragraph, and request that the Examiner reconsider and withdraw this ground of rejection.

**Claim Rejections Under 35 U.S.C. § 103(a) (Obviousness)**

The Examiner states that claims 1-10 and 12-21 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kazuo et al. (JP 07-089874), as evidenced by Dictionary.com (<http://dictionary.reference.com/browse/tinge>).

In response to the Examiner's rejection of claims 1-10 and 12-21, but without conceding the correctness thereof, applicant notes that claim 18 has been amended. In addition, applicants respectfully traverse, and maintain that the Examiner fails to establish a *prima facie* case of obviousness against the rejected claims.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been reasonable expectation that the claimed invention would succeed.

The Examiner fails to present a *prima facie* case of obviousness since the cited references at least do not teach or suggest each and every element of claims 1-10 and 12-21.

For example, the Examiner concedes that Kazuo et al. does not teach the use of 1, 5-dipalmitoyl-L-glutamate-succinic acid (DPEA), as required by claim 1. However, to make up for this apparent deficiency, the Examiner makes an unsupported statement that "DPEA is a known species of palmitic acid in the prior art." To the contrary, applicants respectfully point out that DPEA is not known or recognized as a species of palmitic acid. DPEA comprises a palmityl alcohol-derived structure within the molecule, and does not comprise a palmitic acid-derived structure. Indeed, DPEA comprises two palmityl alcohol-derived structures, an L-glutamate-derived structure, and a succinic acid-derived

structure. Further, a carboxyl group within the DPEA molecule is a portion of the succinic acid-derived structure. Accordingly, one skilled in the art could not have understood that DPEA is a species of palmitic acid.

Further, the Examiner states "Kazuo et al. teaches that the carrier also comprises stabilizing agents such as sterols and palmitic acids (p. 7, [0037], line 1 and [0041], lines 1-3)." Applicants note that Kazuo et al. does not teach or suggest that palmitic acid can be used as a stabilizing agent by itself. Paragraph [0041] of Kazuo et al. discloses that "specifically, a derivative comprising a hydrophobic compound of palmitic acid...etc. and the aforementioned compound is desirable." In other words, it is disclosed that palmitic acid is used as a derivative (specifically, a bonded compound) with an "aforementioned compound," wherein the "aforementioned compound" is "a compound of at least more than one aliphatic primary amine or secondary amino group, amidino group, or aromatic primary amine or secondary amino group." See, e.g., paragraph [0040] of Kazuo et al.

DPEA molecules do not contain an aliphatic amino group, an aromatic amino group, or an amidino group. Therefore, the derivative comprising palmitic acid and the "aforementioned compound" described in paragraph [0041] of Kazuo et al. clearly differs from DPEA. Furthermore, DPEA is not a known species of said derivative in the prior art.

Accordingly, the combination and use of DPEA with a phospholipid having a phosphatidylcholine group and a sterol as constituents of the claimed invention is not obvious based on the cited references.

In view of the above remarks, applicants maintains that claims 1-10 and 12-21, as amended, satisfy the requirements of 35 U.S.C. § 103(a), and request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner also states that claims 1-10 and 12-16 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,949,663 to Tsuchida ("Tsuchida").

In response to this rejection of claims 1-10 and 12-16, but without conceding the correctness thereof, applicants respectfully traverse, and maintain that the Examiner fails to establish a *prima facie* case of obviousness against the rejected claims.

Here, the Examiner fails to present a *prima facie* case of obviousness since the cited reference at least does not teach or suggest each and every element of claims 1-10 and 12-16.

For example, as the Examiner concedes, Tsuchida does not teach or suggest the use of DPEA, as required by claim 1. However, the Examiner again makes the same unsupported statement that "DPEA is a known species of palmitic acid in the prior art" in order to make up for this apparent deficiency. As discussed above, DPEA is not known or recognized as a species of palmitic acid.

Thus, Tsuchida fails to teach or disclose all of the elements in at least independent claim 1, and, as a result, claims 1-10 and 12-16 are not obvious in light of Tsuchida.

In view of the above remarks, applicants maintains that claims 1-10 and 12-16, as amended, satisfy the requirements of 35 U.S.C. § 103(a), and request that the Examiner reconsider and withdraw this ground of rejection.

### Conclusion

Applicants maintain that claims 1-10 and 12-21, as amended, and new claims 28 and 29 are in condition for allowance. Accordingly, allowance is respectfully requested.

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If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

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Respectfully submitted,

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